Panel on Dietetic products, Nutrition and Allergies

18 August 2008

MINUTES OF THE 21ST PLENARY MEETING OF THE SCIENTIFIC PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES HELD ON 9-11 JULY 2008

PARTICIPANTS

Panel members:

- Jean-Louis Bresson,
- Albert Flynn
- Karin Hulshof
- Hannu Korhonen
- Pagona Lagiou
- Martinus Løvik
- Rosangela Marchelli
- Ambroise Martin
- Bevan Moseley
- Andreu Palou
- Hildegard Przyrembel
- Sean (J.J.) Strain
- Seppo Salminen
- Stephan Strobel
- Inge Tetens
- Henk van den Berg
- Hendrik van Loveren
- Hans Verhagen

EFSA staff:

- Juliane Kleiner
- Wolfgang Gelbmann
- Leng Heng
- Maria Skarp
- Emanuela Turla
- Silvia Valtueña Martínez

European Commission:

- Basil Mathioudakis[1]

[1] DG Health and Consumer Protection, by teleconference call on 11 July 2008 (am).

1. WELCOME, APOLOGIES FOR ABSENCE

The Chair welcomed all participants to the plenary meeting. Apologies for absence were received from Marina Heinonen. Members welcomed Emanuela Turla as a new scientific officer in the NDA Panel support unit.

2. ADOPTION OF THE AGENDA

The agenda was adopted with changes in the order of items discussed.

3. DECLARATIONS OF INTEREST

In relation to the draft opinions on ice structuring protein (agenda item 8.5), plant sterols (agenda item 9.4) and alpha-linolenic acid and linoleic acid (agenda item 9.6), Hans Verhagen declared having been employed by Unilever until mid-May 2005 and refrained from the discussion for these agenda items. No other declarations of interest were made in relation to the remaining items of the agenda.

4. FEEDBACK FROM EFSA SCIENTIFIC COMMITTEE AND OTHER EFSA PANELS

Members were informed about the inaugural meetings on 10 July 2008 of the two new EFSA scientific Panels, the Panel on food additives and nutrient sources added to food (ANS) and the Panel on food contact materials, enzymes, flavourings and processing aids (CEF), which replace the former Panel on additives, flavourings, processing aids and materials in contact with food (AFC). These two new Panels will carry out work previously allocated to the AFC Panel.

5. GENERAL INFORMATION BY EFSA ON MATTERS RELATING TO THE PANEL

In relation to the draft guidance document by the Scientific Committee (SC) on transparency in risk assessment, comments received from NDA Panel members will be transmitted to the SC for consideration.

6. NDA WORK PROGRAMME RELATED TO HEALTH CLAIMS

The planning for the overall NDA work programme for 2008-2009 was discussed. Priority will be given to the evaluation of Article 13 and Article 14 claims of the Regulation on Nutrition and Health Claims made on foods (EC 1924/2006).

Article 14 claims

To date EFSA has received over 220 Article 14 applications (90% referring to children's health and development and 10% referring to reduction of disease risk claims). For many of the applications, additional information is currently being requested from the applicants. For some of the applications, EFSA went back to the respective National Competent Authority

and the Commission seeking clarification on whether the application would fall in the scope of EC 1924/2006 Health Claims Regulation. The Panel emphasised the need for a co-ordinated harmonised approach on the scope interpretation prior to scientific evaluation by the Panel.

The secretariat pointed out that EFSA is still receiving applications referring to children's development and health.

Article 18 claims

Currently, EFSA has received 5 applications under Article 18 (claims based on newly developed science and/or which include a request for the protection of proprietary data) and these are currently under evaluation.

Article 13 claims

It is expected that the European Commission will send to EFSA the consolidated list on Article 13 claims (around 2500 claims) by end July 2008. From a draft consolidated list of health claims, which was sent to Member States for a final review, the Panel identified several claims, which were considered to be general well-being claims or which could be considered as children claims. These comments will be forwarded to the European Commission.

The European Commission's representative gave some explanation relating to the draft background and the terms of references which will be sent to EFSA together with the consolidated list of health claims. It was emphasised that EFSA should comment on the availability and quality of the available data in order to allow the regulator to judge about the acceptability of health claims in the submitted list. The Commission representative also pointed out that, although the scientific substantiation of health claims is the main consideration, EFSA should also comment on proposed wordings. The NDA panel commented that EFSA can evaluate whether the wordings used to express the claimed effect reflect the scientific evidence, but would not go any further, e.g. to take into account consumer understanding.

The Panel highlighted that relevant information on the characterisation of a food constituent/food including its conditions of use is a key starting point to assess possible efficacy and without such information the Panel will not be able to evaluate the scientific substantiation of a proposed claim, because it is necessary to establish that the food constituent/food for which the evidence is provided is the same one for which the claim is made.

7. NEW REQUESTS FOR SCIENTIFIC OPINIONS

7.1 Isolated isoflavones from soy or red clover in food supplements for menopausal women

A new request was received from the Federal Institute for Risk Assessment of Germany (BfR) for a scientific opinion on the safety of isolated isoflavones from soy or red clover in food supplements. In this request EFSA was also asked to advise on any anticipated beneficial effects from the use of isolated isoflavones in food supplements in humans. The request was accompanied by a BfR expert opinion on 'isolated isoflavones are not without risk' which includes a useful compilation of available scientific data.

With respect to the requested efficacy assessment, the Panel mentioned that several claims on isoflavones and soy foods will be included in the consolidated Article 13 health claim list and that the Panel needs to provide scientific opinions on the substantiation of these claims by summer 2009. The request for a safety assessment of isoflavones will be further discussed within EFSA.

8. NOVEL FOODS

8.1 Draft opinion on Vitamin K2

The draft opinion was introduced by the rapporteur and a revised version will be forwarded to the Panel members for possible adoption at the next Plenary meeting.

8.2 Draft opinion on Safety of 'leaves from *Morinda citrifolia* L.

The draft opinion was discussed and adopted subject to the incorporation of modifications agreed upon by the Panel. The text of the full opinion appears on the EFSA web site, available at: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902043844.htm

8.3 Draft opinion on Safety of 'puree from *Morinda citrifolia* L.

Possible adoption was postponed to the next Plenary meeting.

8.4 Draft opinion on Safety of 'fungal oil from *Mortierella alpina*'

The draft opinion was discussed and adopted subject to the incorporation of modifications agreed upon by the Panel. The text of the full opinion appears on the EFSA web site, available at: http://www.efsa.eu.int/EFSA/efsa_locale-1178620753812_1211902043916.htm :

8.5 Draft opinion on Safety of 'Ice Structuring Protein (ISP)'

The draft opinion prepared by the Working Group on Novel Foods with contribution from the GMO Panel was introduced and discussed.

The opinion was jointly adopted by the NDA and GMO Panels subject to the incorporation of modifications agreed upon. The text of the full opinion appears on the EFSA web site, available at:
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902041128.htm

9. Applications pursuant to Articles 14 and 13(5) of Regulation (EC) No 1924/2006

There was some general discussion on the information to be included in the opinions and the Panel agreed on a harmonised approach for all Article 14 and 13 (5) health claims opinions. The Opinions will include information and conclusion on the characterisation of the food constituent/food, on the relevance of the claimed effect to human health and on the scientific substantiation of the claimed effect which should focus on the studies which are strictly pertinent to the claim. If appropriate, the Panel will also comment on the conditions/restrictions of use and the proposed wording

9.1 Draft opinion on Dairy products and healthy body weight

The draft opinion was discussed and a revised version taking into account the comments made at the meeting will be circulated to the Panel for adoption by written procedure.

Post meeting notes: the opinion was formally adopted by the Panel on 8 August 2008. The text of the full opinion appears on the EFSA web site, available at: http://www.efsa.eu.int/EFSA/efsa_locale-1178620753812_1211902055952.htm

9.2 Draft opinion on Dairy products and dental health

The draft opinion was discussed and a revised version taking into account the comments made at the meeting will be circulated to the Panel for adoption by written procedure.

Post meeting notes: the opinion was formally adopted by the Panel on 12 August 2008. The text of the full opinion appears on the EFSA web site, available at: http://www.efsa.eu.int/EFSA/efsa_locale-1178620753812_1211902055359.htm

9.3 Draft opinion on Femarelle® and bone mineral density

The draft opinion was discussed and a revised version taking into account the comments made at the meeting will be circulated to the Panel for adoption by written procedure.

Post meeting notes: the opinion was formally adopted by the Panel on 4 August 2008. The text of the full opinion appears on the EFSA web site, available at: http://www.efsa.eu.int/EFSA/efsa_locale-1178620753812_1211902055028.htm

9.4 Draft opinion on Plant Sterols and blood cholesterols

The draft opinion was discussed and adopted subject to the incorporation of modifications agreed upon by the Panel. The text of the full opinion appears on the EFSA web site, available at: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902054931.htm

9.5 Draft opinion on NeOpuntia® and blood lipid parameters

The draft opinion was discussed and a revised version taking into account the comments made at the meeting will be circulated to the Panel for adoption by written procedure.

Post meeting notes: the opinion was formally adopted by the Panel on 13 August 2008. The text of the full opinion appears on the EFSA web site, available at: http://www.efsa.eu.int/EFSA/efsa_locale-1178620753812_1211902055135.htm

9.6 Draft opinion on ALA and LA and growth and development of children

The draft opinion was discussed and adopted subject to the incorporation of modifications agreed upon by the Panel. The text of the full opinion appears on the EFSA web site, available at: http://www.efsa.eu.int/EFSA/efsa_locale-1178620753812_1211902055015.htm

9.7 Draft opinion on DHA and ARA and development of brain and eyes

The draft opinion was discussed and a revised version taking into account the comments made at the meeting will be circulated to the Panel for adoption by written procedure.

Post meeting notes: the opinion was circulated to the Panel for adoption by written procedure.

9.8 Draft opinion on Elancyl Global Silhouette® and regulation of body composition

The draft opinion was discussed and a revised version taking into account the comments made at the meeting will be circulated to the Panel for adoption by written procedure.

Post meeting notes: the opinion was formally adopted by the Panel on 12 August 2008. The text of the full opinion appears on the EFSA web site, available at: http://www.efsa.eu.int/EFSA/efsa_locale-1178620753812_1211902055083.htm

9.9 Draft opinion on regulat®.pro.kid IMMUN and immune system of children

The draft opinion was discussed and adopted subject to the incorporation of modifications agreed upon by the Panel. The text of the full opinion appears on the EFSA web site, available at: http://www.efsa.eu.int/EFSA/efsa_locale-1178620753812_1211902054992.htm

10. ANY OTHER BUSINESS

There was no any other business.

11. ADOPTION OF THESE MINUTES

These minutes were adopted by written procedure on 2 September 2008.